



House of Representatives

File No. 698

General Assembly

February Session, 2004

(Reprint of File No. 45)

House Bill No. 5201
As Amended by House
Amendment Schedule "A"

Approved by the Legislative Commissioner
May 1, 2004

**AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR
MEDICALLY NECESSARY FORMULA.**

Be it enacted by the Senate and House of Representatives in General
Assembly convened:

1 Section 1. Section 38a-492c of the general statutes is repealed and the
2 following is substituted in lieu thereof (*Effective October 1, 2004*):

3 (a) For purposes of this section:

4 (1) "Inherited metabolic disease" [means] includes (A) a disease for
5 which newborn screening is required under section 19a-55, as
6 amended; and (B) cystic fibrosis.

7 (2) "Low protein modified food product" means a product
8 formulated to have less than one gram of protein per serving and
9 intended for the dietary treatment of an inherited metabolic disease
10 under the direction of a physician.

11 (3) "Amino acid modified preparation" means a product intended
12 for the dietary treatment of an inherited metabolic disease under the
13 direction of a physician.

14 (4) "Specialized formula" means a nutritional formula for children
15 up to age [three] eight that is exempt from the general requirements
16 for nutritional labeling under the statutory and regulatory guidelines
17 of the federal Food and Drug Administration and is intended for use
18 solely under medical supervision in the dietary management of
19 specific diseases.

20 (b) Each individual health insurance policy providing coverage of
21 the type specified in subdivisions (1), (2), (4), (6), (11) and (12) of
22 section 38a-469 delivered, issued for delivery or renewed in this state
23 on or after October 1, 1997, shall provide coverage for amino acid
24 modified preparations and low protein modified food products for the
25 treatment of inherited metabolic diseases if the amino acid modified
26 preparations or low protein modified food products are prescribed for
27 the therapeutic treatment of inherited metabolic diseases and are
28 administered under the direction of a physician.

29 (c) Each individual health insurance policy providing coverage of
30 the type specified in subdivisions (1), (2), (4), (6), (11) and (12) of
31 section 38a-469 delivered, issued for delivery or renewed in this state
32 on or after October 1, 2001, shall provide coverage for specialized
33 formulas when such specialized formulas are medically necessary for
34 the treatment of a disease or condition and are administered under the
35 direction of a physician.

36 (d) Such policy shall provide coverage for such preparations, food
37 products and formulas on the same basis as outpatient prescription
38 drugs.

39 Sec. 2. Section 38a-518c of the general statutes is repealed and the
40 following is substituted in lieu thereof (*Effective October 1, 2004*):

41 (a) For purposes of this section:

42 (1) "Inherited metabolic disease" [means] includes (A) a disease for
43 which newborn screening is required under section 19a-55, as
44 amended; and (B) cystic fibrosis.

45 (2) "Low protein modified food product" means a product
46 formulated to have less than one gram of protein per serving and
47 intended for the dietary treatment of an inherited metabolic disease
48 under the direction of a physician.

49 (3) "Amino acid modified preparation" means a product intended
50 for the dietary treatment of an inherited metabolic disease under the
51 direction of a physician.

52 (4) "Specialized formula" means a nutritional formula for children
53 up to age [three] eight that is exempt from the general requirements
54 for nutritional labeling under the statutory and regulatory guidelines
55 of the federal Food and Drug Administration and is intended for use
56 solely under medical supervision in the dietary management of
57 specific diseases.

58 (b) Each group health insurance policy providing coverage of the
59 type specified in subdivisions (1), (2), (4), (6), (11) and (12) of section
60 38a-469 delivered, issued for delivery or renewed in this state on or
61 after October 1, 1997, shall provide coverage for amino acid modified
62 preparations and low protein modified food products for the treatment
63 of inherited metabolic diseases if the amino acid modified preparations
64 or low protein modified food products are prescribed for the
65 therapeutic treatment of inherited metabolic diseases and are
66 administered under the direction of a physician.

67 (c) Each group health insurance policy providing coverage of the
68 type specified in subdivisions (1), (2), (4), (6), (11) and (12) of section
69 38a-469 delivered, issued for delivery or renewed in this state on or
70 after October 1, 2001, shall provide coverage for specialized formulas
71 when such specialized formulas are medically necessary for the
72 treatment of a disease or condition and are administered under the
73 direction of a physician.

74 (d) Such policy shall provide coverage for such preparations, food
75 products and formulas on the same basis as outpatient prescription
76 drugs.

This act shall take effect as follows:	
Section 1	<i>October 1, 2004</i>
Sec. 2	<i>October 1, 2004</i>

The following fiscal impact statement and bill analysis are prepared for the benefit of members of the General Assembly, solely for the purpose of information, summarization, and explanation, and do not represent the intent of the General Assembly or either House thereof for any purpose:

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 05 \$	FY 06 \$
Comptroller Misc. Accounts (Fringe Benefits)	Various - Cost	None	Indeterminate

Municipal Impact:

Municipalities	Effect	FY 05 \$	FY 06 \$
Various Municipalities	STATE MANDATE - Cost	Potential	Potential

Explanation

The coverage of medically necessary specialized formula for children over the age of three is not provided under the current state employee plans. The Office of the Comptroller has indicated that there would be an increased cost associated with this expansion of coverage to age eight provided under the bill that cannot be determined at this time. It is anticipated that this cost would be incurred in FY 06 when the state is expected to enter into new health insurance contracts.

The bill's impact on municipal health insurance costs will vary by municipality depending on the current coverage. To the extent that medically necessary infant formula over age three is not covered under a municipality's employee health insurance policy, there would be increased municipal costs to provide it. To the extent that cystic fibrosis screening is not covered under a municipality's employee health insurance policy, there would be increased municipal costs to provide it that are anticipated to be minimal.

House "A" eliminates a significant cost and potential revenue gain

to the Department of Public Health (DPH) and also eliminates a potential significant savings and revenue loss to the University of Connecticut Health Center (UCHC). The amendment further requires health insurance policies to cover medically necessary specialized formula for children to age eight, instead of children up to age three, which results in state and municipal costs as described above.

The amendment removes a provision of the bill that would have required the DPH to institute screening of newborns for cystic fibrosis. This will preclude the agency having to hire staff and purchase needed equipment and supplies. Agency costs of \$224,760 in FY 05 and \$233,015 in FY 06 will be averted, as will fringe benefits costs of \$18,365 in FY 05 and \$49,035 in FY 06. To the extent that there will be less likelihood of the DPH increasing newborn screening fees, a potential revenue gain will be precluded.

The University of Connecticut Health Center will continue to perform in excess of 20,000 cystic fibrosis screens each year. Therefore, the potential significant savings and revenue loss discussed in the original bill's fiscal note will be averted, as will the potential future indeterminate savings to the Department of Social Services.

OLR Bill Analysis

HB 5201 (as amended by House "A")*

AN ACT CONCERNING NEWBORN SCREENING AND MEDICALLY NECESSARY NUTRITIONAL FORMULA FOR CYSTIC FIBROSIS**SUMMARY:**

This bill adds cystic fibrosis to the definition of "inherited metabolic disease" in the insurance statutes. This means that health insurance policies must cover amino acid modified preparations and low protein modified food products prescribed for the treatment of cystic fibrosis.

The bill requires health insurance policies to cover medically necessary specialized formula for children up to age eight, instead of age three. Specialized formula is a nutritional formula that is exempt from the federal Food and Drug Administration's (FDA) general nutritional labeling requirements and is intended for use solely under medical supervision in the dietary management of specific diseases.

The bill also requires health insurance policies to cover the preparations, food products, and specialized formulas on the same basis as other outpatient prescription drugs.

This bill applies to individual and group health insurance policies that are delivered, issued for delivery, or renewed in this state after September 30, 2004 and cover (1) basic hospital expenses, (2) basic medical-surgical expenses, (3) major medical expenses, (4) accidents only, or (5) hospital or medical services.

*House Amendment "A" (1) eliminates a requirement in the original bill that newborns be tested for cystic fibrosis and (2) extends insurers' obligations to cover medically necessary specialized formula to children up to age eight, instead of age three.

EFFECTIVE DATE: October 1, 2004

BACKGROUND***Cystic Fibrosis***

Cystic fibrosis (CF) is a chronic and progressive genetic disease usually diagnosed in childhood that causes mucus to build up and clog many bodily organs, but primarily the lungs and pancreas. It can lead to serious breathing problems, lung disease, malnutrition, and growth and development problems.

There is no cure for CF. Disease management varies widely and generally focuses on treating respiratory and digestive problems to prevent complications, including infections. Treatment usually involves a combination of medications, home treatment methods (including respiratory and nutritional therapies), and specialized care by health professionals.

Food Products

Amino acid modified preparations and low-protein modified food products are intended for inherited metabolic disease dietary treatment under a physician's direction.

FDA Nutritional Labeling Requirements

FDA regulations exempt infant formula from the general nutritional labeling requirements that apply, with exceptions, to products intended for human consumption (21 CFR § 101.9(j)(7)). FDA has separate regulations on infant formulas that exempt from labeling requirements formulas that are represented and labeled for use by infants with inborn metabolic disorders, low birth weights, or unusual medical or dietary problems (21 CFR § 107.3).

FDA distinguishes between two types of exempt formulas: those that are readily available to the general public at retail stores and those that are not. Formulas available at a retail store are typically labeled for dietary management of diseases or conditions that are not clinically serious or life-threatening, even though they may also be labeled for use in clinically serious or life-threatening disorders. Formulas that are not available for general consumer purchase are typically prescribed by a physician and must be requested from a pharmacist. They are labeled solely to provide dietary management for specific diseases or conditions that are clinically serious or life-threatening and generally are required for prolonged periods of time (21 CFR § 107.50).

Legislative History

On March 23, the House referred the original bill (File 45) to the Public Health Committee, which reported it favorably on March 31. On April 6, the House referred it to the Appropriations Committee, which reported it favorably on April 13. On April 15, the House referred it to the Finance, Revenue and Bonding Committee, which reported it favorably on April 21. On April 22, the House referred it to the Planning and Development Committee, which reported it favorably on April 27.

Related bill

SB 107 (File 48), favorably reported by the Insurance and Real Estate Committee and passed by the Senate, requires health insurance policies to cover medically necessary specialized formula for children of any age, instead of children up to age three.

COMMITTEE ACTION

Insurance and Real Estate Committee

Joint Favorable Report

Yea 16 Nay 2

Public Health Committee

Joint Favorable Report

Yea 22 Nay 0

Appropriations Committee

Joint Favorable Report

Yea 50 Nay 0

Finance, Revenue and Bonding Committee

Joint Favorable Report

Yea 40 Nay 1

Planning and Development Committee

Joint Favorable Report
Yea 14 Nay 1